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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BAXTER HEALTHCARE CORPORATION, Plaintiff, v. FRESENIUS MEDICAL CARE HOLDINGS, INC., Defendant.	)	No. 09 C 7566 Judge John W. Darrah

MEMORANDUM OPINION AND ORDER

Plaintiff, Baxter Healthcare Corporation ("Baxter"), brought suit against Defendant, Fresenius Medical Care Holdings, Inc. ("Fresenius"), alleging breach of contract. Before the Court is Baxter's motion for a preliminary injunction. Both parties have submitted declarations and written briefs and agreed that Plaintiff's motion shall be decided without an evidentiary hearing.

BACKGROUND

Baxter and Fresenius provide products and/or services related to dialysis. Dialysis is the process of removing waste and excess fluid from the blood. Patients who suffer from End-Stage Renal Disease ("ESRD") require dialysis in order to survive. The more common form of dialysis is hemodialysis, which is typically performed at outpatient dialysis clinics. This case concerns peritoneal dialysis ("PD"), which may be performed by ESRD patients at home.

Baxter is a leading manufacturer of products for PD. Since 1994, Baxter has sold the HomeChoice cycler (cycler being the term for a PD device). According to Baxter, the

HomeChoice was the first pump-based (rather than gravity-based) cycler, was smaller, lighter and easier to use than other cyclers available at the time and has been the standard of care for patients undergoing automated PD.

Fresenius operates approximately 30 percent of the dialysis clinics in the United States. Fresenius also manufactures PD products, including the Liberty cycler, a pump-based cycler introduced in 2008 that is similar to Baxter's HomeChoice. Prior to 2008, however, Fresenius did not make a pump-based cycler. Instead, Fresenius purchased HomeChoice cyclers from Baxter. Fresenius was, and still is, Baxter's second largest customer of the HomeChoice cycler.

Because a specific prescription is required to use either the HomeChoice or the Liberty, the prescribing physician has the ultimate decision on which brand of cycler will be used. The PD patient may influence the decision by discussing options with the prescribing physician. Additionally, clinical staff at Fresenius clinics, including nurses, may influence the decision of which cycler to use. Nurses may discuss with patients the benefits of one cycler or another. Also, nurses may draft a prescription for a cycler that a physician would then sign. Thus, patients, physicians and the clinical staff all have some role in the decision of which cycler to use.

In 2008, Baxter and Fresenius entered into an agreement ("the Agreement"), which governs the supply of Baxter's PD products to Fresenius. The Agreement provides for "equal footing" for Baxter's PD products in Fresenius clinics (the "Equal Footing clause"). Specifically, the Agreement states:

> A primary purpose of this Agreement is for [Fresenius] and Baxter to respect free choice of therapy modality and to have the PD products and offering of

> [Fresenius] and Baxter, respectively, on "equal footing" in the Member Units.[1] Accordingly, [Fresenius] shall, in the Member Units (i) provide equivalent administration, offering and management of PD Products listed in Schedules A-1 and A-2 (equivalent as compared to the PD products and offering of [Fresenius] and other competitive companies), with no restriction or limitation to physician, clinician, or patient choice; and (ii) provide BAXTER reasonable access, including, without limitation, to the administrative and clinical staff of such centers to allow for the reasonable opportunity for BAXTER to reasonably explain and pursue the utilization of Baxter's PD Products.

(Agreement ¶ 5.b.)

Baxter alleges that Fresenius is violating the Equal Footing clause by "systematically preventing patients from having access to Baxter's PD products." Specifically, Baxter alleges that Fresenius has instructed and/or encouraged the clinical staff at its clinics to place new PD patients on Liberty cyclers rather than the HomeChoice and to switch existing PD patients from the HomeChoice to the Liberty. Baxter cites anecdotal evidence of Fresenius nurses pressing patients to switch from Baxter to Fresenius cyclers. Baxter also cites emails from Fresenius employees, directing that PD patients be placed on Fresenius rather than Baxter cyclers.

Baxter seeks a Court order providing that Fresenius shall not (1) direct or require Fresenius personnel to place patients on Liberty cyclers or refrain from placing patients on HomeChoice cyclers; (2) provide any financial incentives or disincentives to any individual to promote the use of the Liberty cycler or prevent use of the HomeChoice cycler; and (3) take any action that interferes with patient use or education, or health care professionals' ability to

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[1]Member Units are those "dialysis facilities, centers or units" that meet certain criteria set out in the Agreement.

prescribe, recommend, discuss, or learn about the HomeChoice cycler. Additionally, Baxter would have the Court order Fresenius to send a notice to Fresenius employees, setting out their obligations under the Equal Footing clause, as interpreted by Baxter.

LEGAL STANDARD

To obtain a preliminary injunction, the moving party must show (1) "a reasonable likelihood of success on the merits" and (2) "no adequate remedy at law and irreparable harm if preliminary relief is denied." *Graham v. Medical Mutual of Ohio*, 130 F.3d 293, 295 (7th Cir. 1997). If the moving party fails to establish either of these two requirements, the injunction must be denied. *Abbott Laboratories v. Mead Johnson & Co.*, 971 F.2d 6, 11 (7th Cir. 1992) (*Abbott*). However, if the initial burden is met, the court must consider the irreparable harm the non-moving party will suffer if the injunction is granted, balanced against the irreparable harm that would be suffered by the moving party if the injunction is denied, and the public interest. *Id.* at 11-12.

Likelihood of Success on the Merits

The central dispute between the parties is the nature of Fresenius's obligations under the Equal Footing clause. Fresenius argues that the Equal Footing clause is essentially an agreement that Fresenius will keep Baxter products on its formulary[2] and will refrain from taking actions that would have an equivalent effect of removing Baxter products from its formulary. Baxter takes a more expansive view of the clause's requirements. According to Baxter, Baxter's PD

[2]A formulary is a list of products that an outpatient facility will make available to patients upon a physician's prescription. If a physician prescribes a product that is not on a facility's formulary, the physician must refer the patient to a different facility that does have the product on its formulary.

prescription products must receive equal treatment in Fresenius clinics. Fresenius employees, Baxter argues, including nurses, cannot put a "thumb on the scale" in favor of Fresenius products. Thus, if a clinic nurse tells a patient about the benefits of a Fresenius product, the nurse must also tell the patient about the equivalent Baxter product. Fresenius employees, Baxter argues, may not direct or induce nurses to favor Fresenius over Baxter.

The specific language in dispute provides: "[Fresenius] shall . . . provide equivalent administration, offering and management of PD Products . . . with no restriction or limitation to *physician, clinician, or patient choice* . . . ." (emphasis added). The plain meaning of the language is consistent with Fresenius's interpretation. The core of the provision appears to be a promise by Fresenius not to restrict patient or physician choice. This is roughly equivalent to a promise to maintain an item on the formulary. As previously noted, if an item is on the formulary, it may be prescribed by a physician without the patient changing clinics. Thus, Fresenius's reading of this clause appears to be a reasonable interpretation.

Baxter's interpretation of the passage, however, is inconsistent with and not supported by the plain meaning of the provision. Noting that the passage also bars restrictions and limitations on *clinician* choice, Baxter argues that the clause bars Fresenius management from inducing or ordering clinic nurses to favor the Liberty cycler over the HomeChoice. This interpretation depends on a questionable reading of "clinician." Baxter argues that the term includes Fresenius clinic employees, such as nurses, dieticians and social workers, and that they were intended to be included in the provision as "clinicians." Fresenius contends that, in the context of this provision, *clinician* refers to professionals who work in a physician's office, not the nurses that are employed by Fresenius in Fresenius clinics. The later definition is consistent with the clause

as a whole. The Agreement provided and the parties agree that it is the patient and physician who decide which cycler is used. Neither party argues that the clinical staff should be the ones to make that decision. Thus, *clinician* choice, if clinician is taken to mean Fresenius clinic staff, cannot logically promote patient and physician choice. Moreover, Baxter is not arguing that Fresenius employees should have any choice in deciding which cycler to recommend. Rather, Baxter argues the Fresenius employed nurses *must* give equivalent presentations of both the HomeChoice and the Liberty, informing patients of the benefits of both cyclers. Thus, even Baxter does not ultimately contend that the clause preventing restrictions on "physician, clinician, or patient choice" is intended to include Fresenius employed nurses.

In the alternative, Baxter argues that even if its reading of clinician is incorrect, the clause still prevents Fresenius from restricting or limiting patient and physician choice. Baxter asserts that Fresenius violates the clause by having its nurses "put a thumb on the scale" in favor of Fresenius cyclers. The nurses do this, Baxter alleges, by informing patients about the Liberty but not the HomeChoice, by making the Liberty the default cycler that is prescribed and by pressuring or forcing patients using the HomeChoice to switch to the Liberty. Of these actions, only the last can fairly be said to limit or restrict choice. However, Baxter admits that it is competing with Fresenius in the PD cycler market. Both have sales teams that attempt to convince physicians to prescribe their cycler instead of the other's. Thus, it is not unreasonable that Fresenius does not go out of its way to have its own employees market Baxter's products.[3]

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[3]This is not the first litigation between these parties. In 2007, Baxter filed a patent infringement suit against Fresenius, attempting to prevent the Liberty from coming to market. In August 2008, about the time the Liberty first became available, Baxter ceased providing Fresenius PD patients with a number of commonly used non-prescription products. According to Fresenius, this decision "fundamentally and adversely rewrote the economics of the Baxter-

Baxter counters that clinic employees, such as nurses, are distinct from the sales teams. The nurses, Baxter argues, must present the Baxter and HomeChoice in equivalent fashion, favoring neither cycler over the other. The hole in Baxter's argument, however, is that the Equal Footing clause does not say that. Rather, as discussed above, it says that Fresenius shall not restrict or limit physician or patient choice. Nothing in the plain language of the clause prevents Fresenius employees from influencing that choice – for example, by telling a patient about the Liberty cycler or by recommending that a physician prescribe the Liberty. In short, the strict "nurse neutrality" rule Baxter would impose on Fresenius clinic staff members is not found in the plain language of the Agreement.

Turning to Baxter's evidence that Fresenius is violating the Agreement, Baxter has offered the declarations of several individuals, describing what Baxter considers to be violations of the clause. The most serious allegations presented, those that would violate any reading of the Equal Footing clause, involve nurses pressuring or forcing patients to switch cyclers or, in one case, informing a physician that the HomeChoice would not be an option for new PD patients. Baxter presents declarations from two PD patients: K.H., a patient in Greenville, Mississippi, and L.S., a patient in Auburn, Maine. K.H. states that he was pressured by his dialysis nurse to switch from a Baxter cycler to a Fresenius cycler. K.H.'s declaration states: "I have told [my nurse] repeatedly that I do not want to switch and that I am not comfortable with the idea of using a different cycler. [My nurse] still pressures me to switch anyway. She told me that her bosses are requiring her to switch me over to the Liberty." L.S. stated that she switched to a

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Fresenius contract." Baxter's move required Fresenius to incur a separate delivery charge for the non-prescriptive products, which had previously been delivered with Baxter's prescription products.

Fresenius cycler because she "[did] not want to inconvenience the clinic staff by making them support a different cycler." Additionally, Baxter presented a declaration from Dr. Clarence Wheeler, a physician and the Medical Director at a Fresenius clinic in Texas. Dr. Wheeler stated that he had been told by a PD nurse that she was instructed by a Fresenius representative that all new PD patients would be put on the Liberty cycler.

Reviewing the above declarations, the Court finds that they do not support conduct in violation of the Agreement. With respect to K.H.'s allegations, Fresenius has introduced the declaration of Donna Daves, K.H.'s PD nurse. Daves states that it was K.H.'s physician who made the decision to switch K.H. to the Liberty cycler and that after K.H. objected, the physician reversed the decision and kept K.H. on the HomeChoice. With respect to L.S., Fresenius presents the declaration of Irene Perkins, a PD nurse at L.S.'s clinic. Perkins states that L.S. was initially put on Fresenius PD products while at a local hospital that did not use Baxter products. When she returned to the Fresenius clinic, her doctor ordered that she continue using Fresenius products. Finally, with respect to Dr. Wheeler's declaration, there is no indication that there has been a mass shift away from Baxter PD products at Dr. Wheeler's clinic. Dr. Wheeler stated that the PD nurse mentioned in August 2009 that she had heard they would be placing all new PD patients on the Liberty. In September 2009, when Dr. Wheeler followed up with the nurse, she had not heard anything further about the policy change. Dr. Wheeler states that after this second conversation, a Fresenius nurse administrator confirmed that the PD nurse had been told that new patients would be placed on Liberty cyclers. However, Dr. Wheeler's declaration does not indicate whether the nurse administrator confirmed that the policy would actually be put in place, and there is no further evidence that it has.

Overall, Baxter's purported evidence that Fresenius clinical staff is forcing PD patients to switch to Liberty is anecdotal and unconvincing. Baxter presents no actual data regarding the number of patients who have been forced to switch, data showing a decline in usage of Baxter PD products in general at Fresenius clinics, or a drop in the number of new PD patients starting use of the HomeChoice cycler.

In conclusion, Baxter has not shown that the Equal Footing clause entitles it to the injunctive relief sought. The plain meaning of the clause requires only that Fresenius not limit or restrict patient and physician choice. That requirement is consistent with Fresenius keeping Baxter prescription products on its clinics' formularies and thus available should a physician choose to prescribe a product. The restrictions Baxter would have the Court impose on Fresenius clinical staff are found nowhere in the Agreement. Therefore, Baxter has failed to meet its burden of showing a likelihood of success on the merits.

Fresenius's arguments against the issuance of a preliminary injunction based on an adequate remedy at law and laches need not, therefore, be addressed.

CONCLUSION

Because Baxter has failed to show a likelihood of success on the merits, its motion for a preliminary injunction is denied.

Dated: March 16, 2010

JOHN W. DARRAH
United States District Court Judge